UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

July 25, 2013

DP BARCODE:	412109
MRID:	49089500, 49089501, 49089502, 449089503, 49089504, 49089505,
SUBJECT:	Hydris
REG. NO.:	1677-EUR
DOCUMENT TYPE:	Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [X]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
014703	7681-52-9	Sodium hypochlorite

TEST LAB:	Ecolab
SUBMITTER:	Theodore D. Head
GUIDELINE:	Group A and B Product Chemistry
ORGANIZATION:	AD\PSB\CTT
REVIEWER:	Lynette T. Umez-Eronini
APPROVED BY:	Karen P. Hicks
APPROVED DATE:	July 25, 2013
COMMENT:	This product is for non-food use.

L. T. U-E.
7/29/2013

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EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

July 25, 2013

MEMORANDUM

SUBJECT:	Product Chemistry Review for EPA Reg. 1677-EUR Product Name: Hydris DP Barcode: 412109
CODE:	A540; New Product; Non-Fast Track;
DATE DUE:	September 17, 2013
FROM:	Lynette T. Umez-Eronini, Chemist Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
THRU:	Karen Hicks, Team Leader Chemistry and Toxicology Team Product Science Branch Antimicrobials Division (7510P)
TO:	Demson Fuller PM #32/Nathan Motti Regulatory Management Branch II Antimicrobials Division (7510P)
Applicant:	Ecolab Inc.

Lynette T. Umez-Eronini 7/25/2013

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium Hypochlorite	0.0866
Other Ingredient(s):	99.9134
Total:	100.00

BACKGROUND:

On behalf of the registrant, Ecolab Inc., the consultant, Theodore Head, has submitted an application for registration of a non-integrated end-use product, called "Hydris. The product is a disinfectant, sanitizer, virucide, fungicide, mildewcide, bactericide, cleaner, and deodorizer. This product is used on hard non-food contact surfaces and hard, non-porous surfaces.

The original data package included:

1. Application for Pesticide, dated March 25, 2013
2. Basic Confidential Statement of Formula (CSF), dated March 25, 2013.
3. Draft label, pin-punched March 27, 2013.
4. Certificate with Respect to Citations of Data, dated March 20, 2013.
5. Formulator's Exemption Statement, dated March 25, 2013
6. Data Matrix, 3 pages, dated March 25, 2013.
7. MRID 49089500: Transmittal Document/Letter from Registrant to EPA, dated March 25, 2013 and Ecolab, Inc. (2013) Submission of Product Chemistry, Efficacy and Toxicity Data in Support of the Application for Registration of Hydris. Transmittal of 34 Studies. Transmittal of 34 Studies.
8. MRID 49089501: Hiraoka, B. (2012) SDIC-D Dihydrate Product: Product Identity and Composition and Analysis and Certification of Product Ingredients ("Series 61 and 62 Data"). Unpublished study prepared by Nankai Chemical Co. 35p.
9. MRID 49089502: Davis, B. (2013) Chemical Characterization (Disinfectant - Ambient): AquaLogic. Project Number: 1200040. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 64p.
10. MRID 49089503: Davis, B. (2012) AquaLogic: Storage Stability (Disinfectant - Ambient). Project Number: 1200017. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 29p.
11. MRID 49089504: Davis, B. (2012) AquaLogic: Storage Stability (Sanitizer Cleaner & Glass Cleaner - Ambient): Sanitizer Spray Bottle - Ambient Storage. Project Number: 1200018. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 35p.
12. MRID 49089505: Davis, B. (2013) AquaLogic: Storage Stability (Disinfectant - Refrigerated). Project Number: 1200019. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 38p.
13. MRID 49089506: Hellickson, L. (2012) Aqualogic Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Rhinovirus Type 37-260 ppm. Project Number: 1200063. Unpublished study prepared by Ecolab Inc. Ecolab Research Center--Schuman Campus. 69p.
14. Data matrix, 3 pages, March 14, 2013.

A revised data package was reviewed and included:

1. Basic CSF, July 24, 2013.

FINDINGS:

1. Basic CSF, dated March 25, 2013 is obsolete.
2. Basic CSF, dated July 24, 20t3 supersedes all previous Basic CSFs.
3. Basic CSF, dated July 24, 2013 and the label have the same nominal concentration for the active ingredient.
4. Support for wider certified limits to accommodate the extended shelf life of the product is acceptable.
5. All ingredients in this formulation are approved for use in pesticide formulations.
6. Group A product chemistry data requirements applicable to end-use products have been met (see MRID# 4980950t and Table A below).
7. Group B product chemistry data requirements applicable to end-use products have been met (see MRID# 49809501, 49809502, 49809503, 49809504, and 49809505 and Table B).

CONCLUSION:

The Basic CSF, dated July 24, 2013 is acceptable. Group A and Group B Product Chemistry data requirements have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [X] No [ ]
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [ ] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [ ] No [X]

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC(%)	LCL(%)	UCL(%)
Sodium hypochlorite	0.0866	0.1083	0.0693

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No]] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- t0% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List t inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [[No [[Not applicable [X[

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	49809501
830.1600 Description of Materials	A	49809501
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	49809501
830.1670 Formation of Impurities[4]	NA	
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	A	49809501
830.1800 Enforcement Analytical Method[7]	A	49809501
830.1900 Submittal of Samples	A	49809501

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A		49089501
830.6304 Odor	NA		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Product is a known to be an oxidant.	49089501
830.6315 Flammability/ Flame Extension	A	Product does not contain any flammable ingredients.	49089501
830.6316 Explodability	A	Product does not contain any explodable ingredients.	49089501
830.6317 Storage Stability	A		49089502 49089503 49089504 49089505
830.6319 Miscibility[1]	A	Product is not intended for use with oil or a non-polar solvent.	49089501
830.6320 Corrosion Characteristics	A		49089502 49089503 49089504 49089505
830.6321 Dielectric Breakdown Voltage	A	Product is a conducting liquid that will not be used around electrical equipment.	49089501
830.7000 pH[2]	A	Reported 5 values ranging from pH of 9.67 – 10.60	49089501
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	Reported 5 values ranging from 2.40 - 3.00 cps.	49089501
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	Reported 5 values for specific gravity ranging from 1.0000 – 1.0003.	49089501

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7370 Dissociation Constants in Water	A		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water